UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,129	03/19/2004	Debasis Bagchi	31174/30019	8914

4743 7590 08/03/2009

MARSHALL, GERSTEIN & BORUN LLP
233 SOUTH WACKER DRIVE
6300 SEARS TOWER
CHICAGO, IL 60606-6357

EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
08/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,129	BAGCHI ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-11,18,25,32,36-42 and 105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-11,18,25,32,36-42 and 105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 5/20/2009 has been entered.

2. Applicants' submission, filed 5/20/2009, amends Claims 11, 18, 32, 39, and 43, cancels Claims 43, 51-53, 60, 67, 74, 78-85, 93-104, and 106, and presents arguments in response to the Office Action mailed 1/05/2009.

3. Claims 1, 9-11, 18, 25, 32, 36-42, and 105 are pending and are presently under consideration.

4. Applicants' amendments and arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Drawings

5. The drawings are objected to for the following reason: Paragraph [00034] at page 6 of the Specification provides the only description of the contents of Figure 1.

The paragraph states "Figure 1 is a chart showing how administering two compositions; (1) HCA-SX and (2) HCA-SX, chromium and gymnemic acid, which incorporate hydroxycitric acid, effects various factors of **a person**, in accordance with the present invention." (Emphasis added) However, even with this description of Figure 1, Figure 1 can not be interpreted. For example, for "Serum Ghrelin Level", the placebo treated group/individual (?) serum ghrelin concentration is 0.5 ng/ml, the HCA-SX treated group/individual (?) serum ghrelin concentration is -5.2 ng/ml, and the HCA-SX + chromium + gymnemic acid treated group/individual (?) serum ghrelin concentration is -7.8 ng/ml. How can there be a negative concentration? Further, % change values are also given. The placebo % change is 0.6. What is this 0.6% change relative to? Similar problems exist for other measured factors (e.g., Serum Leptin Level). Also, is the body weight of the placebo group/individual 3.5 pounds?

Corrected drawing sheets (or an amendment to the Specification) in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet

submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. **The objection to the drawings will not be held in abeyance**.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 9-11, 18, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Bhaskaran et al., (U.S. 2003/0207942).

Bhaskaran teaches compositions comprising combined potassium-calcium salts of hydroxycitric acid in amounts ranging from about 15 mg to about 3 gm administered up to three times per day, and methods of reducing body weight using said compositions. See Example 3, page 4; page 6, paragraph [0058]; and page 7, claim 24. The reference also teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia cambogia.* See Abstract.

Instant Claim 1 is drawn to a method for decreasing ghrelin levels in a subject in need thereof. Since there is no recitation in the claims as to how one of ordinary skill in the art would determine whether said subject were in need of reduced ghrelin levels, one must go to the instant Specification for such guidance. The Specification discloses that increased ghrelin levels increase food intake in rodents and humans and that ghrelin levels rise sharply shortly before and fall shortly after every meal in obese subjects. The Specification further discloses the present invention provides a method and composition (i.e., hydroxycitric acid) that reduces ghrelin levels to decrease and regulate food intake, increase fat metabolism and provide other additional benefits associated with maintaining healthy body weight. See page 1, paragraphs 3 and 4 and page 2, paragraphs 6-8. Thus, the Specification teaches that subjects in need of reduction of ghrelin levels are those subjects in need of reducing body weight.

Since Bhaskaran teaches the same compound administered at the same amount as the instant claims, the functionality (i.e., decreasing ghrelin levels) would also be the same. See *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) that discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact

inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

8. Claims 1, 9, 10, and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Balasubramanyam et al. teach double group IA and IIA metal salts of hydroxycitric acid, which are useful in beverage and various food product formulations without affecting their flavor and properties. The group IA metals include potassium and the group IIA metals include calcium (as required by instant Claim 105). See column 1, 1st paragraph and column 2, lines 23-27. The reference teaches hydroxycitric acid is derived from the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See column 1, 2nd paragraph. Balasubramanyam et al. also teach hydroxycitric acid useful in weight reduction. See column 1, 3rd paragraph.

As discussed in the anticipation rejection to Bhaskaran (*supra)*, administration of a composition comprising hydroxycitric acid and it salts as taught by Balasubramanyam et al. would naturally have the same functionality (i.e., decreasing ghrelin levels) as the instantly claimed compositions and methods. See *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 9-11, 18, 25, 32, 36-42, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raju, G. (WO 99/03464), in view of Policapelli et al. (U.S. Patent No. 5,612,039), Allen, A. (U.S. Patent No. 5,480,657), Alviar et al. (U.S. Patent No. 6,413,545), and Balasubramanyam et al. (U.S. Patent No. 6,160,172).

Raju teaches hydroxycitric acid compositions that comprise both calcium and potassium for use in the reduction of body weight. See the Abstract. The source of the hydroxycitric acid is found in the rind of the fruits of *Garcinia* species, as, for example, *Garcinia cambogia*. See page 1, lines 21-23, as well as page 3, lines 21-24. As required by instant claims 11, 18, and 25, a suitable dosage ranges from about 15 to

about 3000 mg of hydroxycitric acid up to three times per day (15 to 9000 mg hydroxycitric acid per day). See page 10, lines 18-24.

Policappelli teaches the administration of dietary compositions for weight loss comprising *Garcinia cambogia* in addition to *Gymnema sylvestre* extract and chromium bound to nicotinate. See claim 8, column 10, where, as required by instant claim 32, the administration of the composition is three times daily before a meal.

Allen teaches compositions for treatment of weight gain comprising caffeine, as for example, in tea, in addition niacin-bound chromium. See the Abstract. As required by instant Claims 41 and 42, the chromium is present in an amount of approximately 5 mcg to 500 mcg. See lines 1-2, column 9.

Alviar teaches compositions for managing body weight comprising effective amounts of *Garcinia cambogia* extract and *Gymnema sylvestre* extract (comprising gymnemic acid). Alvair teaches the daily effective amount of Gymnema *sylvestre* extract is from about 27 to about 293 mg. See column 3, lines 58-62. The open language of the present claims allows for the inclusion of any number of additional active agents.

The teachings of Balasubramanyam et al. are presented *supra*.

As previously discussed, present Claim 1 is drawn to a method for decreasing ghrelin levels in a subject in need thereof. Since there is no recitation in the claims as to how one of ordinary skill in the art would determine whether said subject were in need of reduced ghrelin levels, one must go to the instant Specification for such guidance. The Specification discloses that increased ghrelin levels increase food intake

in rodents and humans and that ghrelin levels rise sharply shortly before and fall shortly after every meal in obese subjects. The Specification further discloses the present invention provides a method and composition (i.e., hydroxycitric acid) that reduces ghrelin levels to decrease and regulate food intake, increase fat metabolism and provide other additional benefits associated with maintaining healthy body weight. Thus, the Specification teaches that subjects in need of reduction of ghrelin levels are those subjects in need of reducing body weight.

As discussed *supra*, the hydroxycitric acid compositions and methods taught and suggested by the prior art would have the same functionality (e.g., decreasing ghrelin levels) of the instantly claimed hydroxycitric acid compositions. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is

enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). "[T}he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed.Cir. 1999).

With respect to claimed dosage ranges of the active agents in the instant compositions and methods of use, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art. Such determination would have been made in accordance with a variety of factors. These would have included such factors as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, in the absence of evidence to the contrary, the currently claimed specific dosage amounts and dosage regimens are not seen to be inconsistent with the dosages that would have been determined by one of ordinary skill in the art.

In view of the combined references set forth *supra*, one skilled in the art would have been motivated to prepare a composition comprising hydroxycitric acid, optionally bound to calcium and potassium or as a dual salt of calcium and potassium, that is derived from the plant *Garcinia cambogia*, optionally further comprising gymnemic acid, tea, niacin-bound chromium and caffeine, in methods to reduce body weight. Such would have been obvious in the absence of evidence to the contrary because each of the claimed components in Applicants' compositions is disclosed in the prior art for the purpose of reducing body weight. Based on the discloser in the instant Specification that present invention provides a method and composition (i.e., hydroxycitric acid) that reduces ghrelin levels to decrease and regulate food intake, increase fat metabolism and provide other additional benefits associated with maintaining healthy body weight, the hydroxycitric acid compositions and methods of treating obesity taught by the cited prior art would also be treating a patient in need of decreasing ghrelin levels.

Response to Arguments

Applicants argue '[t]he anticipation rejections over Bhaskaran and Balasubramanyam should be withdrawn because decreased ghrelin levels cannot be considered inherent in all compounds that are associated with weight reduction". Applicants argue that although the prior art discloses that hydroxycitric acid is administered to aid in weight reduction, there is nothing in the prior art that teaches hydroxycitric acid decreases ghrelin levels. Further, Applicants state "The present claims do not represent a mere added benefit of administering HCA to suppress

appetite, but rather claim a new use of the compound to treat patients in need of decreased ghrelin levels. Such patients might not have a need for appetite suppression and would not have been treated by the prior art administration of HCA. Instead, such patients might be in need of decreased ghrelin levels to regulate secretion of pituitary growth hormone (GH), as well as GHS-Rs distributed in hypothalamic neurons and in the brainstem." Applicants assert most overweight subjects have low ghrelin levels and would not appear to be in any need of reducing their ghrelin levels and many subjects with high ghrelin levels are not overweight. Applicants provide references allegedly in support of these statements (Exhibit A: "Ghrelin", http://arbl.cvmbs.colostate.edu/hboods/pathphys/endocrin/gi/ghrelin.html, and Exhibit B: Marchesini et al., J. Clinical Endocrinology and Metabolism, Vol. 88, No. 12, 5674-5679 (2003)).

Applicants' arguments potentially raises written description and enablement issues with regard to the instant invention.

As previously discussed (*supra*) instant Claim 1 is drawn to a method for decreasing ghrelin levels in a subject in need thereof. Since there is no disclosure in the claims as to how one of ordinary skill in the art would determine whether said subject were in need of reduced ghrelin levels, one must go to the instant Specification for such guidance. The Specification discloses that increased ghrelin levels increase food intake in rodents and humans and that ghrelin levels rise sharply shortly before and fall shortly after every meal in obese subjects. The Specification further discloses the present invention provides a method and composition (i.e., hydroxycitric acid) that

reduces ghrelin levels to decrease and regulate food intake, increase fat metabolism and provide other additional benefits associated with maintaining healthy body weight. See page 1, paragraphs 3 and 4 and page 2, paragraphs 6-8. Thus, the Specification teaches that subjects in need of reduction of ghrelin levels are those subjects in need of reducing body weight.

Upon consideration of Exhibits A and B submitted by Applicants, the Examiner notes that Exhibit A teaches that "[i]n both rodents and humans ghrelin functions to increase hunger th[r]ough its action on hypothalamic feeding centers…[which] makes sense relative to increasing plasma ghrelin concentrations observed during fasting." See page 1, "Regulation of energy balance:". Further, Exhibit A teaches ghrelin "is a prominent target for development of anti-obesity treatments…[and it] has been reported that immunization of rats against ghrelin resulted in decreased weight gain and adiposity relative to control rats, even though both groups consumed an equivalent amount of food." See page 2, 1st paragraph. Exhibit B teaches ghrelin leads to increased body weight. It has been studied as a possible cause of obesity (see page 2, "Introduction", 1st two sentences). Thus, the references provide additional support for the application of the prior art with regard to the instant claims.

Applicants argue "[t]he rejection under 35 U.S.C. §103(a) over Rajuin view of one or more of Policappelli, Allen, Alvair, and Balasubramanyam should be withdrawn because the [instant] claims are directed to methods for decreasing ghrelin levels in subjects in need thereof by administering sufficient amounts of hydroxycitric acid (HCA)

and there is no teaching in the art that administration of HCA would reduce ghrelin levels.

Applicants' arguments are not persuasive for the same reasons discussed above with regard to the rejections under 35 U.S.C. §102.

Conclusion

12. Claims 1, 9-11, 18, 25, 32, 36-42, and 105 are rejected.

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is (571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614